AUG 2 0 2003
K030957

SUMMARY OF SAFETY AND EFFECTIVENESS

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT

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OFFICIAL CORRESPONDENT

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TRADE NAME: Milvella Perfect Capsule

COMMON NAME: Accessory to a Phacoemulsification Device

CLASSIFICATION NAME: Ophthalmic Cannula

DEVICE DESCRIPTION

The Perfect Capsule is a single-use, sterile instrument molded from silicone and designed for use in cataract surgery for the purpose of removing residual cortex and/or epithelial cells after cataract extraction by phacoemulsification. This device provides a method of holding the empty lens capsule and containing irrigation fluid to within the lens capsule after cataract removal, thus reducing the risk of irrigating fluid contacting other ocular structures including the corneal endothelium.

INDICATION FOR USE

The Milvella Perfect Capsule is intended to be used after phacoemulsification of the natural crystalline lens by providing a method for sealed capsule polishing and irrigation, for the purpose of removing residual cortex and/or epithelial cells.

PREDICATE DEVICES

The Milvella Perfect Capsule is substantially equivalent to the following predicate devices:

Company:	Katena
Device:	Ophthalmic Cannulas
510(k):	Class I, exempt
Company:	Advanced Surgical Products, Inc.
Device:	Prisma Disposable Capsule Polishers
510(k):	K874969, K874974, K874985
Company:	Chiron Vision Corp.
Device:	Site Simcoe Style I/A Handpiece
510(k):	K842458
Company:	Advanced Surgical Products, Inc.
Device:	Prisma Disposable Simcoe I/A Cannula
510(k):	K874973

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS

The intended use of the Perfect Capsule does not differ from the legally marketed predicate device(s). The technological differences between the Perfect Capsule and the predicate device(s) are related to the method for creating vacuum, and the smaller vacuum channel width. However, these differences do not raise new questions of safety and effectiveness.

SUMMARY OF PERFORMANCE DATA

The Milvella Perfect Capsule complies with the following standards, practices, and guidance's:

STERILIZATION

- ANSI/AAMI/ISO 11137-1994, *Sterilization of Health Care Products – Requirements for Validation and Routine Control – Radiation Sterilization .*
- ANSI/AAMI/ISO 10993; *Biological Evaluation of Medical Devices-Part 1.*

SHELF-LIFE AND PACKAGING INTEGRITY

- ANSI/AAMI/ISO 11607-1997, *Packaging for Terminally Sterilized Medical Devices.*
- AAMI TIR, Guidance for ANSI/AAMI/ISO 11607-1997, *Packaging for Terminally Sterilized Medical Devices, 1997.*

Additionally, performance testing and clinical testing were conducted to establish the functionality and safety of the Perfect Capsule.

CONCLUSION

Since the Milvella Perfect Capsule meets the requirements of the stated standards and has technological characteristics and intended use similar to the predicate devices, the Perfect Capsule is safe and effective and performs in a fashion consistent with its intended use as well as the intended use of the predicate device(s).

Based on the 510(k) statements (21 CFR 807) and the information provided herein, Milvella Pty. Ltd. concludes that the Perfect Capsule is substantially equivalent to the predicate devices under the Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 2 0 2003

Milvella Pty. Ltd.
c/o Judy F. Gordon, D.V.M.
ClinReg Consulting Services, Inc.
2 Delphinus
Irvine, CA 92612

Re: K030957
Trade/Device Name: Milvella Perfect Capsule™
Regulation Number: 21 CFR 886.4670
Regulation Name: Phacofragmentation System
Regulatory Class: Class II
Product Code: HQC
Dated: March 25, 2003
Received: March 27, 2003

Dear Dr. Gordon:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

2. INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K030957

Device Name: Perfect Capsule

Indications for Use:

The Milvella Perfect Capsule is intended for use after phacoemulsification of the natural crystalline lens for the purpose of removing residual cortex and/or epithelial cells, by providing a method for sealed capsule polishing and irrigation.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K030957

Prescription Use ✓ *OR* *Over-The-Counter Use* ____

(Optional Format 1-2-96)